

REMARKS

Claim 24 has been amended to incorporate the limitations of claim 25, which has been canceled accordingly, and to recite that the plant line is a *Brassica napus*, *Brassica juncea*, or *Brassica rapa* plant line. Claim 24 also has been amended to indicate that seeds of the second *Brassica* plant line have an oleic acid content of at least 82%. Claims 24, 32-33, 35, and 39-40 have been amended to delete the term "about." Support for the claim amendments can be found throughout the specification including, for example, at page 13, lines 10-11, page 14, lines 25-28, page 19, lines 3-5, Table 17, and original claims 26-31. New claims 45 and 46 recite the oleic acid content of seeds of the second *Brassica* plant line. Support for new claims 45 and 46 can be found throughout the specification, including page 19, lines 3-5, Table 17, and original claim 24. Applicants also have amended the specification to update the status of the priority applications. No new matter has been added. Applicants respectfully request reconsideration and allowance of claims 24, 26-41, and 45-46 in view of the above amendments and following remarks.

Applicants have not received an initialed page 1 (copy attached) of the Form PTO-1449 submitted with the Information Disclosure Statement of November 17, 2003. It is noted that pages 2 and 3 of the same Form PTO-1449 were initialed by the Examiner and were enclosed with the Office Action mailed on August 6, 2007. Applicants respectfully request that an initialed page 1 of the Form PTO-1449 be returned to Applicants in the next communication, indicating that the references have been considered.

Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejected claims 24-33, 35, and 39-40 under 35 U.S.C. §112, second paragraph, as being indefinite with respect to the phrase "at least about." Claims 39-40 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite with respect to the phrase "less than about." The Examiner asserted that "at least" and "less than" specify a minimum value and "about" implies that the minimum can be less.

While Applicants disagree with the Examiner, the term "about" has been deleted in claims 24, 32-33, 35, and 39-40 to expedite prosecution. The amendment to claims 24, 32-33, 35, and 39-40 does not affect the scope of these claims.

Rejection under 35 U.S.C. §112, first paragraph, for lack of written description

The Examiner rejected claims 24-41 under 35 U.S.C. §112, first paragraph, for lack of written description. The Examiner asserted that Applicants do not describe a method of making any Brassica plant species/seeds and further asserted:

Applicants fail to describe a representative number of Brassica species/seeds which are required to practice said method. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of any Brassica plant species/seeds with said oil content. Hence, Applicants fail to meet either prong of the two-prong test set forth by Eli Lilly. Furthermore, given the lack of description of the necessary elements essential for any Brassica plant species/seeds with said oil content, it remains unclear what features identify any Brassica plant species/seeds with said oil content. Since the genus of any Brassica plant species/seeds has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

The Examiner also asserted that

The Applicant has not adequately described the starting materials. Applicant claims a method of making any plant with 82% monounsaturated fatty acids (MUFA) by crossing any 1st plant with greater than or equal to 45% erucic acid with any 2nd plant with at least about 84% oleic acid. It is well known in the art that not all plants can be successfully crossed to just any plant. Applicant seeks to exclude others from crossing any said plants, but the fact is that some of said plants simply can not be crossed with some other of said plants. Moreover, even among Brassica species, successfully crossing some species with others is known to be essentially impossible.

Applicants disagree with the Examiner. In an effort to expedite prosecution, however, independent claim 24 has been amended to refer to a *Brassica napus*, *Brassica juncea*, or *Brassica rapa* plant line. *B. napus*, *B. juncea*, and *B. rapa* each are oil-producing species and are closely related to one another. See, for example, page 14, lines 25-27 of the present specification and pages 458-460 of "Principles of Cultivar Development", Vol. 2, 1987, Fehr, W., ed. (copy

attached). Please note that Fehr refers to *B. campestris* instead of *B. rapa*. *B. campestris* is a synonym for *B. rapa*, as shown by the attached printout from the Taxonomy Browser of the NCBI. Quazi et al. (Theor. Appl. Genet. (1998) 75:309-318; cited by Examiner on page 8 of the Office Action) indicate that *B. napus* and *B. campestris* cross naturally and produce fertile hybrids. See page 309 of Quazi. See also column 7, lines 20-35 of Wong (U.S. Patent No. 5,638,637, cited by Examiner on page 11 of the Office Action), which indicates that traits can be transferred between *B. napus* and *B. campestris* using conventional plant breeding techniques. Traits also have been transferred between *B. napus* and *B. juncea*. See, for example, page 460 of Fehr.

The specification provides sufficient written description for the recited *Brassica* plant lines. In particular, the specification indicates at page 13, lines 10-11 that the disclosed method can be applied to all oilseed *Brassica* species, and to both Spring and Winter maturing types within each species. The specification also indicates at page 14, lines 25-28 that oil-producing species such as *B. napus*, *B. juncea*, or *B. rapa* are preferred organisms.

The specification indicates that *Brassica* plant line HEC01 is a high erucic acid line that is useful and is sold under the trade name Hero. Other high erucic acid lines such as Venus, Mercury, Neptune, and S89-3673 have erucic acid contents of 50% or greater and also can be used. See, page 19, lines 5-9 of the specification. Thus, the specification provides numerous examples of high erucic acid *Brassica* lines that can be used in the claimed method.

The specification indicates that suitable high oleic acid lines have an oleic acid content of at least 82%. Example 5 and Table 17 provide examples of suitable high oleic acid lines, including Q508, Q4275, and 93GS34-179. Q508 has an oleic acid content of 84.9%. Q4275 has an oleic acid content of 82.1% and has been deposited with the American Type Culture Collection under Accession No. 97569. See for example U.S. Patent No. 6,342,658 (copy attached). 93GS34-179 was obtained by crossing Q4275 to the variety Cyclone. 93GS34 has an oleic acid content of 85% and retained the agronomically desirable characteristics of Q4275. See, for example, page 34, lines 15-19 and Table 17 of the specification. Thus, the specification

provides numerous examples of high oleic acid *Brassica* lines that can be used in the claimed method.

In view of the above, Applicants submit that the claimed methods have more than adequate written description in the specification as filed. The Examiner is requested to withdraw the rejection of claims 24-41 under 35 U.S.C. §112, first paragraph, for lack of written description.

Rejection under 35 U.S.C. §112, first paragraph, for lack of enablement

The Examiner rejected claims 24-41 under 35 U.S.C. §112, first paragraph, for lack of enablement. The Examiner asserted that Applicants do not teach a method of making any *Brassica* plant species/seeds and have not adequately taught the starting materials. The Examiner cited Quazi (Theor. Appl. Genet. (1998) 75:309-318) as evidence that successfully transferring genes from *B. napus* or *B. campestris* to *B. oleracea* is difficult. Applicants disagree.

One of ordinary skill in the art can practice the claimed methods without undue experimentation. As discussed above, independent claim 24 has been amended to refer to a *Brassica napus*, *Brassica juncea*, or *Brassica rapa* plant line. *B. napus*, *B. juncea*, and *B. rapa* each are oil-producing species and are closely related to one another. See, for example, page 14, lines 25-27 of the present specification and pages 458-460 of "Principles of Cultivar Development", Vol. 2, 1987, Fehr, W., ed. (copy attached). In addition, the Quazi et al. reference indicates that *B. napus* and *B. campestris* cross naturally and produce fertile hybrids. See page 309 of Quazi. Traits also have been transferred between *B. napus* and *B. juncea*. See, for example, page 460 of Fehr. Thus, one of ordinary skill would know that interspecific crosses can be used to introduce and transfer traits among *B. napus*, *B. rapa* and *B. juncea* to practice the claimed method. See, e.g., Fehr at pp. 458-460 and 462; specification at page 42, line 3 to page 43, line 2, and page 32, lines 16-29. No undue experimentation would be required for one of ordinary skill in the art to practice the claimed method.

The Examiner also asserted that the "invention appears to employ novel cultivars" and that the "specification does not disclose a repeatable process to obtain the cultivar, and it is not apparent if the cultivar is readily available to the public." Applicants disagree.

The specification indicates that *Brassica* plant line HEC01 is a high erucic acid line that is useful and is sold under the trade name Hero. Other high erucic acid lines such as Venus, Mercury, Neptune, and S89-3673 have erucic acid contents of 50% or greater and also can be used. See, page 19, lines 5-9 of the specification. Neptune seed is maintained by the Department of Plant Science, University of Manitoba, Winnipeg, Manitoba. See, page 344 of McVetty et al. (cited by Examiner on page 11 of Office Action and also submitted as reference AGG on Form-1449 submitted with Information Disclosure Statement of November 17, 2003). Similarly, the Department of Plant Science, University of Manitoba maintains seed for Mercury and Venus. See, page 206 of Scarth et al. (reference APP on Form-1449 submitted with Information Disclosure Statement of November 17, 2003) and page 342 of McVetty et al. (reference AFF on Form-1449 submitted with Information Disclosure Statement of November 17, 2003), respectively. Thus, high erucic acid lines are publicly available and no deposit is necessary.

The specification indicates that suitable high oleic acid lines have an oleic acid content of at least 82%. Example 5 and Table 17 provide examples of suitable high oleic acid lines, including Q508, Q4275, and 93GS34-179. Q4275 has been deposited with the American Type Culture Collection under Accession No. 97569. See for example U.S. Patent No. 6,342,658 (copy enclosed). Thus, a suitable high oleic acid line is publicly available.

93GS34-179 was obtained by crossing Q4275 to the variety Cyclone. 93GS34 retained the seed fatty acid composition and agronomically desirable characteristics of Q4275. See, for example, page 34, lines 15-19 of the specification. Thus, the fatty acid composition of Q5275 can be transferred to other *Brassica* lines. Thus, the specification provides a repeatable method for making suitable high oleic acid lines.

In view of the above remarks, the Examiner is requested to withdraw the rejection of claims 24-41 under 35 U.S.C. §112, first paragraph, for lack of enablement.

Rejection under 35 U.S.C. §103

The Examiner rejected claims 24-41 under 35 U.S.C. §103 as being unpatentable over Wong (U.S. Patent No. 5,638,637) in view of McVetty (Can. J. Plant Sci. 76:343-344 (1996)) and further in view of Downey (Can. J. Plant Sci. 43:271-275 (1963)) in light of Siebel and Pauls (Theor. Appl. Genet. 77:489-494 (1989)). The Examiner asserted it would have been *prima facie* obvious to one of ordinary skill in the art to use the prior art high erucic acid line of Hero or Neptune in a cross with the high oleic acid line of Wong for the purposes of producing a variety of oil containing rapeseeds containing a range of both oleic acid and erucic acid. The Examiner also asserted that one skilled in the art would have been motivated to generate the claimed invention because both oils have commercial value as taught by Wong and Seibel and that one would have a reasonable expectation of success because methods of breeding for oil quality in rape were known in the art and because desired traits can be transferred using conventional plant breeding techniques as taught by Wong. The Examiner further asserted that it was known in the art that the levels of erucic acid can be fixed at a large number of values ranging from 1-60%. Applicants disagree.

As the Supreme Court recently clarified, obviousness under § 103 requires consideration of the factors set forth in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), including an analysis of the scope and content of the prior art and the differences between the claimed subject matter and the prior art. An explicit rationale for why one having ordinary skill in the art would have combined the elements in the manner claimed must be set forth. Indeed, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." See, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 14 (2007), 2007 WL 1237837 (quoting *In re Kahn*, 441 F.3d 997, 988 (Fed. Cir. 2006)).

The Examiner asserted that Wong teaches a method of selecting a plant that produces seeds having a long chain monounsaturated fatty acid content of at least about 82% with an

erucic acid content of about 0.06% and cited to column 7, lines 10-50 of Wong. The Examiner also stated that Wong does not teach an erucic acid content of at least about 15%.

Wong indicates that erucic acid has deleterious effects on human health and indicates it would be useful to increase the oleic acid content of canola (which refers to oil containing <2% erucic acid). See Wong at column 1, lines 18-30 and column 5, lines 14-16. Wong mutagenized *Brassica napus* seeds and selected for lines that had increased oleic acid content (>79%) in seeds. See, e.g., Wong at column 5, line 25 through column 6, line 35. Wong indicates that once the high oleic acid trait is established by mutagenesis, it can be transferred by conventional plant breeding. See column 7, lines 10-20 of Wong. Wong does not direct a person of ordinary skill to a method of making a *Brassica* plant producing seeds in which a high erucic acid line is crossed with a high oleic acid line and progeny are selected that produce seeds having a long chain monounsaturated content of at least 82%, where the erucic acid content is at least 15%.

The McVetty, Downey, and Siebel references do not remedy the deficiencies of Wong. McVetty teaches that Neptune is a high erucic acid line. Downey indicates that erucic acid content is not controlled in a dominant fashion. Siebel indicates that erucic acid content in *Brassica napus* is simply inherited and controlled by two genes acting in an additive manner. Siebel indicates that high erucic acid oils are useful as lubricants. Siebel also indicates that strong negative correlations between erucic acid and C18 fatty acids were observed, i.e., as erucic acid levels increase, oleic acid and linoleic acid levels decrease, or alternatively, as oleic acid and linoleic acid levels increase, erucic acid levels decrease. See, page 493 of Siebel.

The combination of cited references does not direct a person of ordinary skill in the art to make a plant in which the monounsaturated content is distributed among long chain fatty acid acids. As indicated in the specification, the long chain monounsaturated fatty acid content is distributed primarily among oleic acid (C18:1), eicosenoic acid (C20:1), and erucic acid (C22:1). The heterogeneous nature of the long chain monounsaturated fatty acids in the seed oil triacylglycerols confers desirable properties to the oil, including desirable low temperature properties, oxidative stability, and high fluidity characteristics. See, page 18, lines 25-30 and page 20, lines 10-22 of the specification. In contrast, the cited references indicate that either

high erucic acid oils are useful or high oleic acid oils are useful. Thus, the combination of cited references does not render the presently claimed method obvious. The Examiner is requested to withdraw the rejection of claims 24-41 under 35 U.S.C. §103.

CONCLUSION

For at least the foregoing reasons, Applicants submit that claims 24, 26-41, and 45-46 are in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent at the telephone number below if such will advance prosecution of this application. Please apply the Petition for Two-Month Extension of time fee, and any other charges or credits, to deposit account 06-1050.

Respectfully submitted,

Date: _____

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